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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation, SHERR-UNA BOOKER, an individual, Plaintiff, v. C. R. BARD, INC., a New Jersey corporation and BARD PERIPHERAL VASCULAR, INC., an Arizona corporation, Defendants.	No. 2:15-MD-02641-DGC **DEFENDANTS' REPLY IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT OF PLAINTIFF SHERR-UNA BOOKER'S CLAIMS** (Assigned to the Honorable David G. Campbell) **(Oral Argument Requested)**

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Plaintiff seeks to avoid summary judgment by (a) impermissibly citing numerous internal Bard documents and deposition testimony, which have no bearing on Bard's Motion and/or are taken out of context;[1] (b) ignoring clear Georgia law; and (c) asking this Court to create previously unrecognized duties to warn and a new cause of action under Georgia law. For these reasons, and as discussed more fully below and in Bard's Motion, the Court should grant summary judgment on Plaintiff's claims.[2]

A. Plaintiff's Failure to Warn Claims (Counts II, VI) and Misrepresentation Claims (Counts VIII, XII) Fail as a Matter of Law.

1. Bard Had No Duty To Warn about Comparative Risks.

Plaintiff admits that, before treating Ms. Booker, Dr. D'Ayala knew the potential complications of the G2 Filter that were included in the IFU. (Pl. CSOF ¶ 8.) Indeed, Plaintiff admits that the IFU for the G2 Filter warns of the precise risks of complications that Plaintiff experienced. (Pl. CSOF ¶ 5; *Cf.* Pl. Br. at 1.) Specifically, she admits "[t]here is no dispute Dr. D'Ayala was aware the filter he implanted in Ms. Booker could fracture; nor is there any dispute that her filter's IFU included a risk of fracture as a potential complication." (Pl. Br. at 14.) Rather, Plaintiff challenges the adequacy of "Bard's warnings . . . because they did not disclose that the risk of fracture for the G2 was

[1] As part of her response papers, Plaintiff filed a 52-page "Omnibus Separate Statement of Facts" (Doc. 7950). The District of Arizona Local Rule 56.1(b) does not require a moving party to reply to a "controverting statement of facts" or respond to a non-moving party's "additional facts." Accordingly, Bard is not filing such a reply or response here. As noted throughout this Reply Brief, however, these allegations do not raise a genuine issue of material fact that would preclude summary judgment. Instead, Plaintiff's reference to these allegations appears to be largely an attempt to "pack" the summary judgment record with irrelevant allegations (e.g., allegations about filters that Plaintiff did not receive). To be clear, Bard disagrees with Plaintiff's characterization of many of these alleged "facts," even if such disagreement does not raise a genuine issue of material fact.

[2] Bard is entitled to summary judgment on Plaintiff's Manufacturing Defect (Counts I, V) and Failure to Recall/Retrofit (Count VI) claims, as Plaintiff has now withdrawn them. (Pl. Br. at 1 n.1.) Despite refusing to withdraw them during pre-motion meet-and-confer efforts when Bard identified the total absence of factual and legal support, Plaintiff now admits in Response to Bard's Motion what she knew then, that she lacked any evidence to support her manufacturing defect claims, (Pl. CSOF ¶¶ 33-35), and that her recall/retrofit claim was not recognized under Georgia law. Plaintiff's attorneys were well aware of those same facts during the meet and confer process, as evidenced by their withdrawal of the same claim under the same law in the *Jones* case.

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greater than the risk of the same complication for its competitors' devices or as against the SNF." (*Id.*) Yet Plaintiff cites no case law supporting a ***duty*** to include the type of information that she generally demands, such as "warnings that its filters fractured, migrated, tilted, and perforated patients' IVCs at rates significantly higher than competitor IVC filters and Bard's SNF." (Pl. Br. at 6.) Further, Plaintiff does not address the case law cited in Bard's Motion that rejected arguments that manufacturers had a duty to include comparative rate information in their warnings.

Instead, Plaintiff conflates the issues of duty to warn with adequacy of the warning. The existence of a duty to warn is a question of law and is informed by logic, science, and public policy. *See Certainteed Corp. v. Fletcher*, 300 Ga. 327, 330, 794 S.E.2d 641, 645 (2016). Plaintiff argues that Bard had a duty to warn physicians that the G2 Filter "has significantly higher complication rates than the rates for competitor IVC filters and the SNF." (Pl. Br. at 12.) The cases that Plaintiff cites, however, do not address whether such a duty exists, but rather focus on whether adequacy of the warning at issue was a question of fact for the jury. The predicate issue, however, is whether such a duty to warn exists. As a matter of logic, science, and public policy, Bard submits that it has no duty to warn about comparative rates.

First, there is no Georgia law creating a duty on a manufacturer to provide comparative rates of complication for its product to other similar products on the market. Rather, as discussed on page 9 of Bard's Motion, courts that have addressed the issue have found that pharmaceutical and medical-device manufacturers have ***no*** duty to warn physicians about the risks attendant to other products. Plaintiff did not address any of these cases in her Response, and none of the cases that she cites hold that such a duty exists.[3]

[3] *Watkins v. Ford Motor Co.*, 190 F.3d 1213, 1219-20 (11th Cir. 1999) (the court did not discuss whether Ford had a legal duty to provide comparative warnings, but noting that where the rollover risk for the Bronco II was higher than other cars, "a reasonable fact finder could conclude that Ford was required to provide a more detailed warning for the vehicle"); *Cason v. C.R. Bard, Inc.*, No. 1:12-CV-1288-MHS, 2015 WL 9913809, at **3-4 (N.D. Ga. Feb. 9, 2015) (although Bard argued that it had no duty to warn about comparative rates, as noted by the court, the court never addressed Bard's argument,

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Second, Bard is unaware of any FDA regulation that would require (or even permit) it to warn doctors about comparative rates of risk between the G2 Filter and other IVC filters. Any comparative rate information that Plaintiff claims Bard should have included in its warnings is almost certainly precluded by FDA regulations. In the closely related pharmaceutical context, the FDA places strict limitations on when comparative claims can be made, requiring that such comparative information be the result of "adequate and well-controlled studies." *See* 21 C.F.R. § 201.57(c)(7) (2011); 21 C.F.R. § 314.126(b) (2011); *Mut. Pharm. Co., Inc. v. Bartlett*, 133 S. Ct. 2466, 2473 (2013) (state law statute requiring labeling changes preempted). Moreover, Plaintiff's regulatory expert, Dr. Parisian, testified that, per FDA regulations, Bard would not be permitted to provide the rates Plaintiff purports to require in her warnings. (Dep. Tr. Dr. Suzanne Parisian, 71:5-18, Sept. 25, 2014 ("the MAUDE database, it can be used for certain things, but it's not – you wouldn't use it across industry to come up with the incidence rate. And it says it on the database; don't use it as an incidence rate, but you can come up with – you can use it for certain things, but I wouldn't use it for that"), attached as Exhibit N).

Further, generating reliable comparative adverse event rates across IVC filters is impossible, and therefore the rates are not the result of "adequate and well-controlled studies." If Plaintiff's proposed comparative warnings standard were imposed on Bard when the FDA's regulations most likely would prevent Bard from providing such comparative warnings, then the Plaintiff's claim would be preempted by federal law. *See Bartlett*, 133 S. Ct. at 2473; *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (state requirements preempted if "'different from, or in addition to' the requirements imposed by federal law"); *Bass v. Stryker Corp.*, 669 F.3d 501, 505-06 (5th Cir. 2012) (affirming

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instead skipping ahead to whether the warning was adequate); *Cisson v. C.R. Bard, Inc.*, No. 2:11-CV-00195, 2013 WL 5700513, at *7 (S.D. W. Va. Oct. 18, 2013), *aff'd sub nom.* 810 F.3d 913 (4th Cir. 2016) (not addressing whether Bard had a duty to warn about rate and severity of complications, instead summarily noting that the issue was whether Bard's warnings were adequate, which is a question of breach; thus, the court skipped the predicate step of whether a duty actually existed to warn about rates of complications); *In re Mentor Corp.*, 711 F. Supp. 2d 1348, 1377 (M.D. Ga. 2010) (discussing adequacy of warning only, not whether a duty existed to warn about comparative rates of complication).

order dismissing failure to warn claims, on the basis they were foreclosed by *Riegel*).

Third, meeting Plaintiff's demand that Bard provide comparative warnings to doctors is impossible. The data is inherently unreliable for defining actual rates. The FDA explicitly states that "MAUDE data is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices." (MAUDE – Manufacturer and User Facility Device Experience, *at* https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127891.htm (last accessed Oct. 23, 2017)).[4] Even Plaintiff's biostatistician expert, Dr. Betensky, recognizes in her analysis that she is not deriving actual rates of complication, rather calling them "Reporting Risk Ratios."

Finally, even if rates for adverse events were discernible, because they would be discernible only through adverse event reports, the rates would change many times each day. Adverse events for IVC filters (the numerators in the rates calculation) are reported throughout the country. Moreover, Bard reports to the FDA the events that it receives through new legal complaints, and certain events reported in medical literature. Additionally, Bard's filters and other filters (the denominators in the rates calculation) are implanted many times throughout the country each day, thereby altering the denominator in any rate calculation. Thus, throughout each day, the numbers needed to calculate the comparative rates change for every IVC filter. By the time that Bard could compile the

[4] *See also* Goldman (writing for the U.S. Food and Drug Administration), *Limitations and Strengths of Spontaneous Reports Data*, 20 Clinical Therapeutics C40 (1998) (discussing the many biases in spontaneous adverse event reports, and concluding that "Numerator and denominator limitations make incidence rates computed from spontaneously reported data problematic, if not completely baseless"), attached as Exhibit O; FDA, *Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment* (Mar. 2005) (discussing the numerous biases inherent in adverse event reporting, and concluding that "Comparisons of reporting rates and their temporal trends can be valuable, particularly across similar products or across different product classes prescribed for the same indication. However, such comparisons are subject to substantial limitations and interpretation because of the inherent uncertainties in the numerator and denominator used. As a result, FDA suggests that a comparison of two or more reporting rates be viewed with extreme caution and generally considered exploratory or hypothesis-generating. Reporting rates can by no means be considered incidence rates, for either absolute or comparative purposes."), attached as Exhibit P.

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comparative rate data, calculated comparative rates of risk, and informed doctors of the results, the rates would be wrong. Bard then would need to issue revised warnings documents, which likewise would be wrong by the time they were issued to doctors. Considering the volume of filter-related complications across all devices that can potentially occur each year and that tens of thousands of IVC filters are placed each year, Plaintiff's demand for comparative rates warnings is simply impossible to meet.

For all of these reasons, the Court should decline to impose a duty on Bard to warn about comparative rates of complications, and should grant Bard summary judgment on Plaintiff's failure-to-warn claims.

2. Bard's Warnings Were Adequate as a Matter of Law.

Because Plaintiff admits that the IFU for the G2 Filter warns of the precise risks of complications that Plaintiff alleges she experienced, Bard's warnings were adequate as a matter of law. Although adequacy of warnings is sometimes a question of fact, in situations such as these, Georgia courts have found such warnings adequate as a matter of law. *See, e.g., Thornton v. E.I. Du Pont De Nemours & Co., Inc.*, 22 F.3d 284, 289 (11th Cir. 1994) (applying Georgia law, and finding "[t]he product carried a warning of the hazards connected with its use. Said warning was reasonably calculated to reach the average user and contained clear and simple language. . . . Summary judgment is appropriate where, as in this case, the facts support only one conclusion, that is, the warning and its communication were adequate."); *Lakey v. Mentor Corp.*, Civil Action No. 1:05–cv–929–TCB, 2007 WL 4811929, at *4 (N.D. Ga. Mar. 30, 2007) (finding that failure to warn claim was barred because plaintiff alleged that product caused infection and product insert sheet warned of the risk of infection). As discussed in Bard's Motion, the IFU's warnings clearly conveyed the risks of Bard's filter, and Dr. D'Ayala was aware of those risks when prescribing the G2 as a retrievable filter.[5] Therefore, the Court should

[5] Plaintiff's assertion that "Dr. D'Ayala testified that he read and relied upon the G2 IFU," is incorrect. (Pl. Br. at 6.) Plaintiff has no evidence that Dr. D'Ayala "read" the G2 IFU. (*Cf.* Pl. Supp. OSOF ¶ 331). Dr. D'Ayala only testified that he agreed he had the G2 IFU "available" to him before he implanted Ms. Booker. (Pl. CSOF ¶ 4.) Additionally, Plaintiff's assertions that Dr. D'Ayala intended her G2 filter to be a permanent device, (Pl.

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find the warnings adequate as a matter of law.

Additionally, while Plaintiff argues for several pages about alleged information contained in Bard documents, she ***never*** identifies the precise information/language Bard's warnings should have contained. *See Nolley v. Greenlee Textron, Inc.*, No. CIVA 1:06-CV-228 MHS, 2007 WL 5369405, at *6 (N.D. Ga. Dec. 6, 2007) (granting summary judgment because "given the Court's exclusion of [the plaintiff's expert's] testimony, plaintiff lacks essential expert evidence as to what alternative warnings should have been given and whether such warnings would have been heeded. . . . Indeed, without [the expert's] opinion, the jurors will not be presented with alternative warnings and will have no means by which to adjudge whether the existing warnings were adequate.") Because Plaintiff has provided no evidence by which a jury can determine whether the warnings were adequate, summary judgment is appropriate on her failure to warn claims.

3. Plaintiff Cannot Prove Proximate Causation.

As Bard discussed in its Motion, an element of Plaintiff's failure to warn claim is that a purported proper warning would have caused a different product to be used, thereby avoiding the Plaintiff's alleged injuries. (*See* Mot. at 10-11.) Plaintiff presents no evidence to satisfy this element of her claim. As such, Plaintiff's failure to warn claims fail as a matter of law.

Plaintiff did not ask Dr. D'Ayala during his deposition whether a different warning would have changed his decision to use the G2 Filter for Ms. Booker. Instead, Dr. D'Ayala was asked would he have "liked to have known" certain information contained in internal Bard documents regarding the Recovery Filter "as a doctor who is implanting

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Br. at 3, 12), ignores his testimony on cross examination that, based on his own language in the operative note identifying the device as a retrievable filter, he intended the G2 to be retrieved when she was no longer contraindicated. (Dr. D'Ayala Dep. Tr., 89:18 to 93:3, Mar. 21, 2017, ("D'Ayala Dep. Tr. Supp.") attached as Exhibit C-1.) This is true even though the G2 was not cleared for retrievable indication in 2007, because "I can tell you that we had retrieved a number of these G2 filters." (*Id.* at 84:22 to 85:11.) Because Plaintiff has taken Dr. D'Ayala's testimony out of context, and contends that Bard has done the same, Bard submits his entire deposition transcript.

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Recovery filters." (Pl. Supp. OSOF ¶¶ 332-339; Pl. Br. at 6-7.)[6] Ms. Booker did not receive a Recovery Filter. For example, Plaintiff's counsel asked whether information contained in the Recovery Filter Migration Remedial Action Plan is "important to you to know prior to implanting a ***Recovery Filter***?" (*Id.* at ¶ 337 (Pl. Ex. B-B, D'Ayala Dep. at 37:22-40:2 (emphasis added).) Contrary to Plaintiff's inaccurate assertion, Dr. D'Ayala ***never*** testified that "He may have used a filter other than a Bard Filter." (*Id.* at ¶ 335.) His complete testimony relates, again, to information contained in an internal Bard document showing reported complication rates for the ***Recovery Filter***, not the G2 Filter at issue here:

> Q. This is a health hazard evaluation . . . dated December 17th, 2004 . . . And this is ***Recovery Filter*** Consultants Report . . . to Bard of adverse events associated with the ***Recovery*** . . . Would this have been important information for you to know, that is, a doctor who is implanting ***Recovery filters***, that those filters [Recovery Filters] had a greater risk of fracture that's four and five times higher than the competitor filters?
>
> A. Yes.
>
> Q. Is that the type of information that would influence your prescribing habits, whether you would use that filter, a Bard filter, or another filter?
>
> A. Yes.

(*Id.* (Pl. Ex. B-B, D'Ayala Dep. at 36:12 to 37:20 (emphasis added; objections omitted).[7]

[6] Plaintiff's only questioning related to information specific to the G2 filter admittedly was based on information that post-dated Ms. Booker's implant by three years. (*See* Pl. Supp. OSOF ¶ 340; Ex. C-1, D'Ayala Dep. Tr. Supp. at 61:6-25 ("Q. I know this is dated 2010, but I'm going to ask you the question for purposes of a hypothetical, that is, had you known this information of this conclusion [in the 2010 Nicholson article], would that have influenced your prescribing habits and the use of the G2 with Ms. Booker?" A. Yes.").) Plaintiff relied on the reported (12%) and extrapolated (25%) fracture rates in the 2010 Nicholson article to ask whether Dr. D'Ayala "would have used a G2" had he known back in 2007 that there was a 12 or 25 percent risk of filter fracture with the G2. (Pl. Supp. OSOF ¶ 340.) Dr. D'Ayala questioned the science behind the conclusions in the Nicholson article, (*Id.*, Pl. Ex. B-B, D'Ayala Dep. at 70:6-8), and admitted that this information from 2010 was not available to him when he implanted the G2 filter in Ms. Booker in 2007. (Ex. C-1, D'Ayala Dep. Tr. Supp. at 116:11-21.)

[7] Plaintiff relies on other testimony that is not admissible (and was properly objected to at the time it was solicited) because the question had no foundation and mischaracterized the doctor's previous testimony. (*See* Ex. C-1, D'Ayala Dep. Tr. Supp. at 61:6-25); *see also*

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In fact, Dr. D'Ayala admitted that it would be "[d]ifficult to say with certainty" whether the information he was shown would have changed his prescribing decision, and that it "would depend upon what other filters we had at the time and what their problems would have been." (SSOF at ¶ 11). Plaintiff's evidence that he "***may*** have used a filter other than a Bard filter," (Pl. Supp. OSOF ¶ 335),[8] "raises merely a conjecture or possibility," which is insufficient to establish causation as a matter of law. *See, e.g.*, *R & R Insulation Servs., Inc. v. Royal Indem. Co.*, 705 S.E.2d 223, 233 (Ga Ct. App. 2010) ("[P]laintiff must present evidence supporting a reasonable inference that the warning provided by the defendant would prevent the injury. An inference cannot be based upon evidence which is too uncertain or speculative or which raises merely a conjecture or possibility."); *Nelson v. Pima Comm. College*, 83 F.3d 1075, 1081-82 (9th Cir. 1996) (citations omitted) ("[M]ere allegation and speculation do not create a factual dispute for purposes of summary judgment."); *Watkins v. Eli Lilly & Co.*, No. 1:08-CV-1665, 2010 WL 11493785, at *8 (N.D. Ga. Mar. 31, 2010) (citations omitted) (Plaintiff must prove "but for the inadequate warning, the physician would not have used or prescribed the product. If a plaintiff fails to meet this burden, the causal connection is broken, and plaintiff cannot prove that the breach was the proximate cause of his injuries.").

Critically, Dr. D'Ayala unequivocally testified that he does not rely on information contained in a medical device manufacturer's internal documents, or their preliminary or internal investigations, when deciding which IVC filter to use because such incomplete information is unreliable, misleading, and could negatively impact his practice. (*See* Pl. CSOF ¶ 14.) Contrary to Plaintiffs' claim, this testimony is not taken out of context.

Pl. Supp. OSOF ¶ 339 (Pl. Ex. B-B, D'Ayala Dep. at 63:10 to 64:7).) This inadmissible testimony cannot be used to oppose summary judgment.

[8] Dr. D'Ayala's testimony that he would "have used a different device if I knew at the time that the Bard filter was not ideal or as good as some of the other implants," or "if there was a different filter that I knew of that was better, in terms of its safety profile," (Pl. Supp. OSOF ¶¶ 338-339), is insufficient to create a question of fact because it is speculation. Similarly, his testimony based on information that post-dated Ms. Booker's implant by three years, (*see id.* at ¶ 340), is insufficient to support proximate causation as a matter of law.

Rather, it clarifies Dr. D'Ayala's testimony earlier in his deposition regarding whether the Recovery Filter information he was shown would have changed his prescribing habits. Importantly, "Plaintiff does not dispute that this testimony was given by Dr. D'Ayala." (*Id.*) Instead, Plaintiff asks this Court to consider his earlier, speculative testimony based on mischaracterized facts, from internal Bard documents, over his later clarified testimony.

For each of these reasons, the Court should find the G2 Filter's warnings adequate as a matter of law.

4. Plaintiff Offers No Legal Authority For Separate Products Liability Misrepresentation Claims (Counts VIII, XII).

Plaintiff baldly asserts that "misrepresentation claims survive summary judgment in Georgia." (Pl. Br. at 15.) But "Plaintiff does not provide any authority to support its negligent misrepresentation claim, and summary judgment on Plaintiff's negligent misrepresentation claim [should be] granted." *Gaddy v. Terex Corp.*, No. 1:14-CV-1928-WSD, 2017 WL 3476318, at *5 (N.D. Ga. May 5, 2017) ("This Court previously determined that, under Georgia law, 'there [are] no misrepresentation claims for products liability distinct from failure to warn claims.' *Brazil v. Janssen Research & Dev. LLC*, 249 F. Supp. 3d 1321, 1340 (N.D. Ga. 24, 2016) (citing *Swicegood v. Pliva, Inc.*, 543 F. Supp. 2d 1351, 1357 (N.D. Ga. 2008) ("In the absence of clear precedent, I am not prepared to recognize the viability of misrepresentation claims distinct from products liability or failure to warn claims.")").

"[C]ourts in many states [including Georgia] have expressly rejected the argument that misrepresentation claims are distinct from product liability or failure-to-warn claims. The rule in these states is that all claims arising from the use of a product are properly characterized as 'product liability claims.'" *In re Darvocet, Darvon & Propoxyphene Prod. Liab. Litig.*, 856 F. Supp. 2d 904, 910 (E.D. Ky. 2012) (citing *Swicegood*, 543 F. Supp. 2d at 1357), *aff'd sub nom. In re Darvocet, Darvon, & Propoxyphene Prod. Liab. Litig.*, 756 F.3d 917, 943 (6th Cir. 2014) (predicting based on the *Swicegood* opinion that

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the Georgia Supreme Court would construe Plaintiffs' misrepresentation claims as product liability claims).

Plaintiff's attempt to distinguish the case law that Bard cited is unavailing. The *Swicegood* court specifically distinguished *Potts v. UAO-GA AG CHEM, Inc.*, 567 S.E.2d 316, 318 (Ga. Ct. App. 2002) because the misrepresentation claim that the *Potts* court contemplated did not "deal[] with a products liability claim," but rather the employer's misrepresentation about the plaintiff's "*exposure* to chemicals." *Swicegood*, 543 F. Supp. 2d at 1357. Therefore, *Potts* does not support Plaintiff's misrepresentation claims here as they are not founded on any alleged misrepresentations regarding her specific exposure to the Filter. Instead, like the *Swicegood* court found, Plaintiff's misrepresentation claims are simply "'masquerading' as a products-liability claim," (Pl. Br. at 16.), and do not differ from her failure-to-warn claims. Put simply, "Plaintiff does not address the legal basis for her claim, cite any case law, or distinguish the cases cited by Defendants. Nor does Plaintiff explain how a negligent misrepresentation claim differs from a failure to warn claim." *Brazil*, 249 F. Supp. 3d at 1340 (dismissing misrepresentation claim).

Further, even if Georgia law recognized separate products liability misrepresentation claims, Plaintiff's claims fail on the merits. (*See* Mot. at 6 n.3.) Plaintiff offers no evidence of the required elements, including scienter and justifiable reliance. (*See* Pl. CSOF ¶¶ 10, 17, 29-31);[9] *see, e.g.*, *Potts*, 567 S.E.2d at 319; *Swicegood*, 543 F. Supp. 2d at 1357 (justifiable reliance is an essential element of both negligent and fraudulent misrepresentation under Georgia law). Thus, Bard is entitled to summary judgment on Plaintiff's misrepresentation claims.

[9] Plaintiff admits that Dr. D'Ayala does not recall specific conversations with any Bard sales representatives, including Robert Ferrara. (*See* Pl. CSOF ¶ 10.) Therefore, the Court should ignore Plaintiff's thinly-veiled attempt to create a question of fact with Robert Ferrara's deposition testimony. (*See* Pl. Br. at 7-8; Pl. Supp. OSOF ¶¶ 345-358.) Similarly, Dr. D'Ayala testified as to what information, if any, would have impacted his decision to prescribe the G2 Filter in this case, which is the only opinion that is relevant on this issue. All other testimony should be ignored. (*See* Pl. Br. at 8-9.)

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B. Plaintiff's Negligence *Per Se* Claim (Count IX) Fails.

Plaintiff's negligence *per se* cause of action fails because she admittedly is using a Georgia statute as a vehicle to privately enforce alleged FDCA violations. (*See* Pl. Br. at 16 ("Count IX of Plaintiff's Master Complaint alleges that Bard was negligent *per se* and based upon violation of several sections of the Food Drug and Cosmetic Act including but not limited to, 21 U.S.C. §§ 321, 331 and 352, and various attendant regulations, specifically 21 C.F.R. §§ 1.21, 801, 803, 807 and 820."). The FDCA, however, does not provide a private right of action for a defendant's violation of its provisions. *See Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 810 (1986).

Instead, "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). This Section "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). Accordingly, where "the existence of these federal enactments is a critical element in [Plaintiff's] case," and where Plaintiff's claims "exist solely by virtue of the FDCA . . . requirements," state law claims are impliedly preempted by the FDCA. *Id.* at 352-53 (finding fraud-on-the FDA claims involving 510(k)-cleared device impliedly preempted).

Negligence per se raises precisely the type of state-law claim *Buckman* held preempted, because such claims "exist solely by virtue" of the FDCA, and have FDA violations as a "critical element." *Id.*; *see generally Arvizu v. Medtronic Inc.*, 41 F. Supp. 3d 783, 793 (D. Ariz. 2014) ("The Court concludes that Plaintiffs' [negligent off-label promotion] claims are impliedly preempted because they 'exist solely by virtue' of FDCA requirements. Allowing Plaintiffs' claims to go forward would be essentially authorizing an impermissible action to enforce the provisions of the FDCA.").

Plaintiff fundamentally misunderstands the Supreme Court's preemption jurisprudence, and misconstrues *Leonard v. Medtronic Inc.*, 2011 WL 3652311 (N.D. Ga. Aug. 19, 2011). The *Leonard* Court held that the plaintiffs' negligence *per se* claim was

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"impliedly preempted by § 337(a)," based on the implied preemption principles established in *Buckman*, because it sought to privately enforce the FDCA. *Id.* at *8; *see also Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1327 (11th Cir. 2017) ("[I]mplied preemption prohibits state-law claims that seek to privately enforce duties owed to the FDA."). Contrary to Plaintiff's contention, (*see* Pl. Br. at 17), this holding was not predicated on the device's PMA status (which would be entitled to *express* preemption under § 360k(a)). Moreover, implied preemption is not limited to PMA devices, as Plaintiff seems to suggest, but rather applies equally to 510(k) devices. Indeed, the very device at issue in *Buckman* was a 510(k) device. Thus, *Leonard* is directly applicable here, Plaintiff's negligence *per se* cause of action is impliedly preempted, and summary judgment is appropriate.[10]

C. Plaintiff Has Offered Insufficient Evidence To Bring a Punitive Damages Claim.

Plaintiff has failed to meet her high burden to establish her punitive damages claim because (1) she has not shown that her allegations involving different products and

[10] Plaintiff argues that O.C.G.A. § 51–1–6 circumvents this preemption, and provides a separate cause of action, but it does not. A large body of case law runs counter to her argument, finding that O.C.G.A. § 51–1–6 is simply a codification of the negligence *per se* doctrine, and a separate statute providing a cause of action is still required. *See e.g.*, *Hanover Ins. Co. v. Carroll*, No. 1:13–cv–01802–SCJ, 2014 WL 5472520, at *7 (N.D. Ga. Mar. 5, 2014) ("[S]upport for a claim under § 51–1–6 must be found in a legislative enactment outside of § 51–1–6."); *Coleman v. H2S Holdings, LLC*, 230 F. Supp. 3d 1313, 1321 (N.D. Ga. 2017) ("[N]one of the three Georgia statutes that Plaintiff claims Oasis violated provides a private right of action. One is a criminal statute, and the other two 'simply set forth general principles of tort law.' They authorize 'the recovery of damages for the breach of a legal duty otherwise arising, though not expressly stated, under a statute or common law.' Since Oasis violated no such duty, those statutes have no application here.") (internal quotations omitted); *see also, Dist. 65 Ret. Tr. for Members of Bureau of Wholesale Sales Representatives v. Prudential Sec., Inc.*, 925 F. Supp. 1551, 1561 (N.D. Ga. 1996) (finding fraud and negligence claims brought under O.C.G.A. § 51–1–6 were preempted by ERISA). The lone case Plaintiff cites in support of her position, *Amick v. BM & KM, Inc.*, 275 F. Supp. 2d 1378 (N.D. Ga. 2003), also recognizes that "[w]here the cited statute does not govern the relationship between the parties, no cause of action exists [under O.C.G.A. § 51–1–6], and recovery of damages based on violation of that particular statute is unwarranted." *Id.* at 1382. The only statute that Plaintiff identifies is the FDCA, which does not permit a private right of action.

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complications[11] are substantially similar to the G2 Filter complications at issue in Ms. Booker's case, and (2) Plaintiff has not shown that Bard acted with "conscious indifference" by doing "nothing," because Plaintiff concedes that the G2 design changes were intended to improve fracture and migration resistance. Punitive damages are only assessed in ***extreme*** cases in Georgia, and require clear and convincing evidence of "willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of a conscious indifference to the consequences" of the tortious act. O.C.G.A. § 51-12-5.1(b).

Plaintiff suggests that a "conscious indifference to the consequences" requires less than some intentional act. (Pl. Br. at 22.) But, Georgia law is clear that "conscious indifference to consequences means an ***intentional*** disregard of the rights of another, ***knowingly or willfully***. *COMCAST Corp. v. Warren*, 650 S.E.2d 307, 311 (Ga. Ct. App. 2007) (citing *Read v. Benedict*, 406 S.E.2d 488 (Ga. Ct. App. 1991)) (emphasis added); *see also Georgia Farm Bureau Mut. Ins. Co. v. Miller*, 473 S.E.2d 189, 191 (Ga. Ct. App. 1996) ("The latter expression relates to an intentional disregard of the rights of another knowingly or willfully disregarding such rights."). Thus, even clear and convincing evidence of gross negligence will not support an award of punitive damages. *COMCAST*, 650 S.E.2d at 311.

1. Plaintiff Cannot Support Her Punitive Damages Claim with Other Incidents Involving Different Products and Complications Without Showing Substantial Similarity.

"In product liability actions, evidence of other incidents involving the product is admissible, and relevant to the issues of notice of a defect and punitive damages, ***provided there is a showing of substantial similarity***. Without a showing of substantial similarity, the evidence is irrelevant as a matter of law." *Ray v. Ford Motor Co.*, 514 S.E.2d 227,

[11] Plaintiff uses the non-descript terms "product," "device," or "its retrievable line of IVC filters" to give the misimpression the cited information is not related exclusively to the Recovery Filter. (*Cf.* Pl. Br. at 20; Pl. OSOF ¶¶ 29, 41, 45, 52, 53.)

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230 (Ga. Ct. App. 1999) (emphasis added). *Ray*, which is instructive here, involved inadvertent vehicle motion of a 1989 Mustang by allowing the ignition key to be removed without the vehicle being in the "park" position. *Id*. at 229. Ford kept a database, much like FDA's MAUDE database on which Plaintiff relies, of prior instances of inadvertent vehicle movement in cars lacking the ignition locking device. But, the prior "incidents were not confined to any particular model or year and that some of the information dated back to the 1960s. Moreover, the information was encoded into the database by employees who had no personal knowledge of the events, but who were simply instructed to input the information from the various source documents into designated codes. The codes utilized were extremely broad, and any one designation could include a wide variety of fact patterns." *Id*. at 230-31. "The database also failed to take into account various underlying factors-such as whether the parking brake was engaged, whether the car was on level ground or an incline or whether the vehicle was unoccupied-because this information was unknown or missing from the source documents." *Id*. Furthermore, "the information in the database has not been verified, and at least some of the information is known to be inaccurate. Ford had also determined that the database contained a number of duplicate entries." *Id.*

In other words, many of the problems inherent in the MAUDE database were also present in *Ray*. (*See e.g.*, Doc. Nos. 7288; 8221 (discussing various reliability issues comparing rates between Bard's retrievable filters, the SNF, and using the MAUDE database, in Bard's motion and reply in support to exclude Dr. Betensky).) The Georgia Court of Appeals found no error in the trial court excluding this evidence and declining to consider it for the plaintiff's punitive damages claim. Likewise, here, Plaintiff's evidence of other incidents cannot support her punitive damages claim because she has made no showing that the documents and testimony that she cites in her Response regarding Bard's other filters and complications are substantially similar to the complications that occurred

with the G2 Filter that Ms. Booker received.[12] *See State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422-23 (2003) ("A defendant's dissimilar acts, independent from the acts upon which liability was premised, may not serve as the basis for punitive damages."). As such, the Court should disregard all such evidence when considering whether the Plaintiff has created a question of material fact concerning her punitive damages claim.

2. Plaintiff Has Not Shown that Bard Exhibited "Conscious Indifference" By Doing "Nothing," Because Plaintiff Concedes The G2 Filter Design Was Intended to Improve Fracture/Migration Resistance.

Plaintiff cannot establish that Bard acted with a "conscious indifference" that would justify imposing punitive damages. Plaintiff relies on *Cason*, which in turn relied exclusively on *Cisson*, for arguing "that punitive damages are available where a manufacturer knows that its product is potentially dangerous and chooses to do *nothing* to make it safer or to warn consumers." (Pl. Br. at 22 (*quoting Cason*, 2015 WL 9913809, at *6 (emphasis original)).) But even the *Cisson* court acknowledged that "[a]ny care taken to prevent injuries would not rise to an 'entire want of care' and could not, by definition, exceed gross negligence." *Cisson v. C.R. Bard, Inc.*, No. 2:11-CV-00195, 2013 WL 5700513, at *13 (S.D.W. Va. Oct. 18, 2013); *COMCAST*, 650 S.E.2d at 311 (clear and convincing evidence of gross negligence will not support an award of punitive damages).

Despite Plaintiff's claim that the G2 was "a newer but equally defective design" to the Recovery Filter, (Pl. Br. at 20), Plaintiff also argues that Bard developed the G2 Filter "with the objective of addressing and minimizing problems of filter migration and filter

[12] Plaintiff does not cite any cases to support the proposition that "substantial equivalence," as defined by FDA regulations and applied in the 510(k) process for product clearance, constitutes "substantial similarity" for purposes of punitive damages. *In re Bair Hugger Forced Air Warming Devices Prod. Liab. Litig.*, No. MDL152666JNEFLN, 2017 WL 1373257, at *2 n.1 (D. Minn. Apr. 13, 2017) (acknowledging "[a]n FDA finding of substantial equivalence in the § 510(k) premarket approval process does not necessarily mean that the device under consideration has the same technological characteristics as the predicate device."). "Without a showing of substantial similarity, the evidence is irrelevant as a matter of law." *Ray*, 514 S.E.2d at 230.

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arm fracture with the Recovery." (Pl. OSOF ¶ 63.) Indeed, Bard made several dimensional changes to the design of the Recovery when developing the G2 Filter aimed at improving fracture and migration resistance. (*Id.* at ¶ 313.) While Plaintiff disputes whether this "redesign" was effective, (Pl. Br. at 21, 23), Bard's intended design improvements, and substantial investment in making those difficult improvements, cannot be considered "nothing" or "an entire want of care which would raise the presumption of a conscious indifference to the consequences." O.C.G.A. § 51-12-5.1(b).[13]

Plaintiff's other assertion is that "Bard never . . . implemented known design improvements to address alarming rates of filter migration and perforation," "even when, in 2008, it identified significant design changes to the G2 that were essential to the safety of the device." (Pl. Br. at 21.) "Bard did not seek and receive 510(k) clearance for its Meridian filter . . . which included caudal anchors (to resist caudal migration) until August 2011." (Pl. Supp. OSOF ¶ 367.) Plaintiff, in essence, alleges that Bard should be liable for punitive damages because it did not invent and bring to market its subsequent generation filters by June 2007 when Ms. Booker received her filter. This assertion ignores that these design changes were not available given the extensive design, testing, and regulatory clearance processes that were required before these design changes could be safely and legally implemented.[14] Put simply, Plaintiff has failed to meet her high burden under Georgia law to "present some evidence of 'willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious indifference to consequences.'" *Edwards v. Ethicon, Inc.*, 30 F. Supp. 3d 554, 564 (S.D. W. Va. 2014) (citations omitted) (applying Georgia law and granting summary judgment on punitive damages claim).

[13] As Plaintiff points out, after the G2 was cleared for permanent indication on August 29, 2005, (Pl. CSOF ¶ 36), Bard continued to evaluate and demonstrate the safety and efficacy of the device via the EVEREST clinical study. (Pl. OSOF ¶ 90.)

[14] Regarding its warnings, Bard's position has always been it is precluded, both legally and practically, from including rates of complications in its IFUs. (*See supra* § A.1.)

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Further, Georgia courts have dismissed punitive damages claims in factually similar circumstances more egregious than Plaintiff alleges against Bard. *See, e.g.*, *Hernandez v. Crown Equip. Corp*., 92 F. Supp. 3d 1325, 1357 (M.D. Ga. 2015) ("[E]ven assuming that most or even all of the 741 accidents were sufficiently similar to the one here to impute constructive notice to Crown, forklift manufacturers clearly have to weigh the benefits of a particular design against the possibility that other risks might be increased" and "Crown was not consciously indifferent" to the risk because it made different design changes other than those proposed by the plaintiff); *Moore v. Wright Med. Tech., Inc*., No. 1:14-CV-62, 2016 WL 1298975, at *6 (S.D. Ga. Mar. 31, 2016) (finding that the plaintiff alleged a viable failure to warn claim because "Defendant published materials in which it claimed to have never experienced modular neck fractures since 1985, even though Defendant knew those statements were false," but such evidence did not justify bringing a punitive damages claim); *Stuckey v. N. Propane Gas Co*., 874 F.2d 1563 (11th Cir. 1989) (affirming the district court's finding that "the evidence did not show [the manufacturer's] culpability rose to a level sufficient to justify an award of punitive damages under Georgia law" even though "[t]he propane industry in general has long been familiar with this phenomenon of 'odor fade'" such that in certain circumstances, leaking propane would become odorless and causing a greater risk of explosions).

By contrast, every case cited by *Cisson* is factually distinguishable and shows that for punitive damages to be available, the defendant must truly do "nothing" in the face of likely and extreme injuries to show such an "entire want of care which would raise the presumption of conscious indifference to consequences." O.C.G.A. § 51-12-5.1; *see, e.g.*, *Weilbrenner v. Teva Pharms. USA, Inc*., 696 F.Supp.2d 1329, 1340; 1344 (M.D. Ga. 2010) (finding that the "warning [for eye complications] was directed to adults only," the FDA required separate warnings for pediatric patients, like the plaintiff, and the manufacturer knew of the condition could lead to blindness and did not warn of it); *Mack Trucks, Inc. v. Conkle*, 436 S.E.2d 635, 640 (Ga. 1993) (punitive damages appropriate

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where evidence showed truck manufacturer ignored or rejected advice multiple times from its engineering division to reinforce frames, vetoed proposals to reinforce frames on new trucks, and failed to notify purchasers of frame problems); *Ford Motor Co. v. Stubblefield*, 319 S.E.2d 470, 476; 481 (Ga. Ct. App. 1984) (analyzing under a different legal standard whether a verdict was excessive, but finding that a manufacturer's "conscious decisions to defer implementation of safety devices" to prevent fuel tanks catching fire in collisions, and that the manufacturer made "no effort was made to inform owners" without the safety devices of the risk, supported punitive damages); *Ford Motor Co. v. Sasser*, 618 S.E.2d 47, 58 (Ga. Ct. App. 2005) (manufacturer was aware of a greater risk to passengers from a seat latching system which caused the seats to collapse in collisions causing spinal cord injuries, knew of an internal "recommendation for a red indicator to alert customers to an unlatched seat, [] its own concerns that a recall may be in order, and despite its intent to change the design of the latching system to remedy this acknowledged safety defect," "chose to do nothing to warn consumers" such as the plaintiff) (emphasis added); *Reid v. BMW of N. Amer.*, 430 F.Supp.2d 1365, 1373-74 (N.D. Ga. 2007) (finding punitive damages issue was for jury where the BMW defendants knew of problems with "radiator[s] explod[ing] causing boiling radiator fluid to spray onto" consumers, and there was "no evidence that *any* warnings existed") (emphasis added).[15]

For all of these reasons, Plaintiff's punitive damages claim fails as a matter of law.[16]

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[15] Plaintiff's other authority, *General Motors Corp. v. Moseley*, 447 S.E.2d 302 (Ga. Ct. App. 1994) and *Mascarenas v. Cooper Tire & Rubber Co.*, 643 F. Supp. 2d 1363 (S.D. Ga. 2009), are inapposite. Unlike in those cases, and contrary to Plaintiff's allegation, Bard did not "ignore proven design changes" or "simple, relatively inexpensive solutions." (Pl. Br. at 2.) To the contrary, Bard made substantial investments innovating and improving the design of its retrievable line of filters to meet continuing patient needs, as Plaintiff concedes, (*See id.* at 23), including conducting rigorous IDE clinical trials testing the safety and effectiveness of many of those designs. (*See* Defs. Mot. Summ. J. Re: Preemption (Doc. 5396), at 22-23; Defs. Reply Mot. Summ. J. Re: Preemption (Doc. 7828), at 6-7.)

[16] Plaintiff's other grounds for punitive damages based on Bard's alleged failure to recall or stop selling its devices, for selling allegedly adulterated devices, and for allegedly

I. Conclusion.

For these reasons, and for the reasons stated in Bard's Opening Brief, Bard respectfully requests that this Court grant Bard's Motion for Partial Summary Judgment.

RESPECTFULLY SUBMITTED this 2nd day of November, 2017.

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failing to provide FDA with complete information also fail. (*See* Pl. Br. at 23.) First, Plaintiff already conceded her failure to recall/retrofit claim. Second, "stop-selling claims" are preempted. *See Bartlett*, 133 S. Ct. at 2477. Third, "No private cause of action exists against [Bard] for selling 'adulterated' devices, no matter how the claim may be styled." *In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig.*, 592 F. Supp. 2d 1147, 1162 n.18 (D. Minn. 2009), *aff'd*, 623 F.3d 1200 (8th Cir. 2010). Finally, attacks on the quality of information underlying FDA's decisions are impliedly preempted. *E.g.*, *Estes v. Lanx, Inc.*, 660 F. Appx. 260, 262 (5th Cir. 2016); *Seufert v. Merck Sharp & Dohme Corp.*, 187 F. Supp. 3d 1163, 1180 (S.D. Cal. 2016); *In re Incretin-Based Therapies Prod. Liab. Litig.*, 142 F. Supp. 3d 1108, 1130-31 (S.D. Cal. 2015). Therefore, any derivative punitive damages predicated on these allegations fail.

CERTIFICATE OF SERVICE

I hereby certify that on this 2nd day of November, 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

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